



A Division of Cell Projects Ltd

ISOHELIX GENEFIX Saliva DNA/RNA Collector conforms to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices

The undersigned, under their sole responsibility, declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

Manufacturer: **Cell Projects Ltd**
Address: **Roebuck Business Park, Ashford Road, Harrietsham, Kent, ME17 1AB, UK**

Authorised Representative Address: **Advena Ltd**
Tower Business Centre, 2nd flr. Tower Street, Swatar, BKR 4013, Malta

Device: **Isohelix GeneFiX Saliva DNA/RNA Collector, Non-Sterile.**
Trade names “GeneFiX Saliva DNA/RNA Collector,”
“GeneFix RNA collector”, “GeneFiX”, “BuccalFiX ”

Basic UDI: **5060544100258QZ**

GMDN Code: **63232**

Intended Use: **Collection of Saliva for research or clinical diagnosis**

Device description: **GeneFiX DNA/RNA Collector consists of a Polypropylene collection funnel, an instruction sheet, 2 foam swabs (GFXA, GFXHA, FDXA and RFXA only) and 1ml (RFX only) or 2ml of stabilizing and lysis solution supplied into either:**

- A Polypropylene 10 ml tube with Polyethylene cap;
- Automation friendly Polypropylene 10 ml tube with Polypropylene cap, both with or without a barcode.

All the components are supplied in bulk or fully sealed into a plastic blister pack.

GFX-25 or 50 and BFX-25 or 50 buffers supplied as bulk solutions in HDPE bottles.

BFX/S1/05 supplied as 0.5ml BLS buffer in 2ml screw capped tube.

Product codes:

GFX-01	GFXH-01	FDX-01	RFX-01
GFX-02	GFXH-02	FDX-02	RFXA-01
GFXA-01	GFXHA-01	FDXA-01	BFX/S1/05
GFX-25	GFX-50	BFX-25	BFX-50

IVDR Assessment Route:

Provide indication of conformity assessment route chosen in accordance with Article 48 of the IVDR.
For **Class A**: Issuing of the Declaration of Conformity in accordance with Article 17 after drawing up the technical documentation in Annexes II and III of the EU IVDR 2017/746.

ISOHELIX GeneFiX DNA/RNA Collector has been developed, and will be manufactured and monitored in accordance with the Quality Management System of **CELL PROJECTS LTD**, based on **ISO 9001:2015** and **ISO 13485:2016**

Signed for and on behalf of **CELL PROJECTS LTD** by

Tom Hole (Managing Director)

Maidstone, UK

